REMARKS

Claims

Claims 1, 4, 8, 11, 16–17 and 21–24 are currently under examination with claims 18–20 withdrawn from consideration due to restriction/election and claims 2, 3, 5–7, 9, 10, and 12–15 cancelled without prejudice or disclaimer.

Claim amendments

The claim dependencies of claims 16 and 21 have been amended. The amendment thereof is deemed to be self-explanatory.

Amended claim 17 and 21 are supported, at least, by the disclosure contained in paragraph [0073] of the published application.

It is respectfully submitted that the claim amendments do not raise new matter nor do they impose additional search burden. See, MPEP §714.13. Entry thereof is earnestly solicited.

Rejection under §112, ¶2

Applicants thank the Examiner for his careful review of the claims. The forgoing amendments render the rejection of claims 16 and 21 under this section moot.

With respect to the rejection of claim 21 for allegedly failing to provide the metes and bounds of the claim term "an additional medicament active ingredient," Applicants have amended the claims to explicitly recite such molecules. No agreement is to be implied. Withdrawal of the rejection is respectfully requested.

Rejection under §103

Claims 1, 4, 8, 11, 16–17 and 21–24 are rejected under §103(a) as allegedly rendered obvious by Sridhar (*Lancet Oncology*, 2003) in view of Arvinte et al. (WO 02/96457). This rejection is respectfully traversed.

The basis for this rejection can be found in page 4 of the Office Action. Therein, the Examiner contends that Sridhar teaches MAb c225 and MAb h425 and the claim element missing from Sridhar's disclosure (for example, antibody concentrations or the means for concentrating antibody formulations) is taught by Arvinte. It is further alleged at page 4 of the Office Action that Arvinte additionally discloses "antibodies may be monoclonal, chimeric antibodies which are humanized, antibody fragments and antibody derivatives which are PEGylated."

Applicants respectfully disagree that Arvinte's disclosure rectifies the limitations in Sridhar. Arvinte discloses concentrated formulations of IgE molecules and methods for preparing such

formulations. There is no disclosure in the cited reference how monoclonal antibodies, such as, for example, MAb c225 or MAb h425 antibodies of the present invention, may be concentrated. Applicant submits that for each individual antibody and especially for each monoclonal antibody a specific method has to be developed to arrive at a preparation of highly concentrated formulations. For example, it was art-recognized that "monoclonal antibodies poses a difficult problem with respect to high concentration, especially if pharmaceutically critical stabilizers should be omitted." See, for example, col. 2 of US patent no. 6,252,055, which was cited in the previous Office Action. As explicitly stated under MPEP §2145, "proceeding contrary to accepted wisdom in the art is evidence of non-obviousness. *In re Hedges,* 783 F.2d 1038, 228 USPQ 685 (Fed. Cir. 1986)." Favorable reconsideration is respectfully requested.

In view of the forgoing remarks, it is submitted that the preparations of the instant invention are unobvious over the totality of the disclosure in the cited references. Withdrawal of the rejection is respectfully requested.

The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,

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